

Report to Congressional Requesters

August 2009

SCHOOL MEAL PROGRAMS

Changes to Federal Agencies' Procedures Could Reduce Risk of School Children Consuming Recalled Food





Highlights of GAO-09-649, a report to congressional requesters

Why GAO Did This Study

Over the past few years, several food recalls, such as for beef and peanut products, have affected schools. It is especially important that recalls affecting schools be carried out efficiently and effectively because young children have a higher risk of complications from food-borne illnesses. GAO was asked to determine how federal agencies (1) notified states and schools about food recalls, (2) advised states and schools about disposal and reimbursement of recalled food, and (3) ensured that recalls were being carried out effectively. To do this, GAO reviewed and analyzed relevant documents and interviewed federal and state officials, as well as officials from 23 school districts that had experience with at least one of four recent cases involving the safety of food in the school lunch program.

What GAO Recommends

GAO recommends that USDA improve FNS notification procedures and instructions on carrying out recalls. GAO also recommends specific steps that USDA and HHS take to improve monitoring of the effectiveness of recalls.

USDA and HHS agreed with this report's recommendations.

View GAO-09-649 or key components. For more information, contact Kay E. Brown at (202) 512-7215 or brownke@gao.gov.

SCHOOL MEAL PROGRAMS

Changes to Federal Agencies' Procedures Could Reduce Risk of School Children Consuming Recalled Food

What GAO Found

Despite its efforts, the U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS), which oversees federal school meals programs, did not always ensure that states and schools received timely and complete notification about suspect food products provided to schools through the federal commodity program. The federal commodity program provides food to schools at no cost to the schools, and accounts for 15 to 20 percent of food served in school meals. During 3 recent recalls, FNS notified states, but in only one case did it inform schools to hold and not serve suspect foods prior to an official recall of commodity products. When a videotape aired by the media showed inhumane treatment of cattle at a plant that provided beef to the commodity program, FNS told states to have schools stop serving the company's beef weeks before the official recall of commodity beef was announced. However, when the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) recalled suspect peanut products and canned vegetables in two other cases, FNS did not inform states and schools to hold and not serve the companies' commodity products until the recalls were expanded to include the companies' commodity productsweeks later. FNS's initial notification to states regarding recalls did not provide complete information on the full range of products affected. Instead, states and schools continued to receive information on multiple other recalled products over time. It sometimes took states and schools a week or more to determine what additional products were subject to a recall, during which time they unknowingly served affected products.

FNS provided instructions for disposal and reimbursement of recalled products to states who, in turn, provided instructions to schools but, nonetheless, some schools experienced problems. Some schools reported to GAO problems in finding landfills that would accept large quantities of recalled products. Some schools also reported that reimbursement instructions were not clear, reimbursement was delayed for months, and that all of their expenses related to the recalls were not reimbursed.

Although both USDA's Food Safety Inspection Service (FSIS) and the FDA procedures direct them to conduct recall quality checks, neither included thousands of schools that had received recalled USDA-commodities products for the beef and peanut recalls because they thought FNS conducted these checks. As a result, they were unable to ensure that the recalls were being carried out effectively by schools. FNS officials said that they did not conduct any kind of systematic quality checks of schools receiving recalled commodities, because they relied on FSIS and FDA to conduct such checks. FDA did include schools in its canned vegetable recall audit checks, and some may have received recalled-commodity canned vegetables. However, because FDA does not systematically sample for schools or analyze results of the quality checks for the group, the agency cannot be assured that the recall was carried out effectively in schools.

Contents

Letter		1
	Background	4
	Despite Its Efforts, FNS Did Not Always Ensure that States and Schools Received Timely and Complete Information about Potentially Dangerous Commodity Products in Three	-
	Companies' Recalls FNS Provided Disposal and Reimbursement Instructions to States,	11
	but State and School Administrators Reported Challenges in Disposing of Products and Obtaining Reimbursement Federal Regulators Did Not Systematically Monitor and Assess the	20
	Effectiveness of Recalls and Holds in Schools	25
	Conclusions	28
	Recommendations for Executive Action	30
	Agency Comments and Our Evaluation	31
Appendix I	Comments from the Department of Agriculture	34
Appendix II	Comments from the Department of Health and Human Services	36
Appendix III	GAO Contacts and Staff Acknowledgments	41
Figures		
	Figure 1: Possible Food Distribution Routes from a Company to Schools	5
	Figure 2: Simple Diagram of How Schools are Notified of	0
	Commodity Recalls Figure 2: A Solved District's Large Overtity of Westley d/Hellmonk	8
	Figure 3: A School District's Large Quantity of Westland/Hallmark Beef Products at a Disposal Transfer Station	22

Abbreviations

AMS	Agricultural Marketing Service
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
FNS	Food and Nutrition Service
FSA	Farm Service Agency
FSIS	Food Safety and Inspection Service
HHS	U.S. Department of Health and Human Services
PCA	Peanut Corporation of America
USDA	U.S. Department of Agriculture

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



United States Government Accountability Office Washington, DC 20548

August 20, 2009

Congressional Requesters

In early 2009, the Peanut Corporation of America (PCA) and more than 375 companies that received or used its products recalled almost 4,000 types of peanut-containing foods for possible Salmonella contamination. A year before, in early 2008, the U.S. Department of Agriculture (USDA) announced the largest food recall in its history when the Westland/Hallmark Meat Packing Company recalled more than 143 million pounds of beef sold over a two-year period. Prior to the recalls, USDA had purchased both peanut products and beef for school meal programs and distributed them as a federally-provided commodity to states to serve in school meals or snacks. Schools also purchased recalled beef and possibly peanut products commercially. While there were no reported illnesses among schoolchildren or the public from consuming recalled beef, almost 700 people were sickened from consuming peanut products, of which onethird were school-aged children between the ages of 5 and 18. The magnitude of these two recalls, and the likelihood that schoolchildren consumed these recalled products, raises overall concerns about the safety of foods served in schools and the welfare of schoolchildren.

USDA's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) are responsible for establishing regulations to ensure the safety of the nation's food supply, while USDA's Food and Nutrition Service (FNS) also works to help ensure the safety of food served in public schools through the federally-supported school meal programs. FSIS is responsible for the safety of meat, poultry, and processed egg products; while FDA is responsible for the safety of virtually all other food products, including grains, nuts, and produce. These regulatory agencies can request that companies voluntarily recall food products that are suspected to be unsafe, adulterated, or mislabeled. Schools are affected by recalled products, when they have received the product as a commodity from USDA or purchased the product commercially on their own. Commodities are foods procured by USDA and provided to states at no charge for schools to serve in school meal programs. School meal programs include the National School Lunch Program, which in addition to providing lunches, provides after school snacks; the School Breakfast Program; and Special Milk Program. Commodities generally account for 15 to 20 percent of the food served in school meals. The remaining 80 to 85 percent of food served in schools is

procured on the commercial market by the schools themselves. While foods schools purchase are only subject to recalls announced by FSIS and FDA, the commodities are also subject to actions announced by FNS for safety and quality reasons. For example, FNS can issue an "administrative hold" on commodities based on the recommendation of FSIS or FDA and in conjunction with the responsible USDA procurement agency, prohibiting schools from using a particular product, pending further investigation, if concerns are raised about its quality and safety. FNS works with state agencies who, in turn, work with local school food authorities in their states to administer the school meal programs and to keep schools informed of food holds and recalls.

Ongoing congressional interest in the safety of the nation's food supply has led to numerous requests for GAO reports and testimonies. For example, in 2004, we reported on USDA and FDA recall programs and procedures to protect consumers from unsafe food and recommended that the agencies better track and manage food recalls, achieve more prompt and complete recalls, and determine if additional ways are needed to alert consumers about recalled food. ¹ In 2007, we added federal oversight of food safety to our high-risk list because of persistent and longstanding problems related to having 15 agencies collectively administer at least 30 food safety-related laws.² We have reported that this fragmented federal structure has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. Recent recalls affecting federally subsidized school meal programs are of particular concern because children are more susceptible to developing complications from food-borne illnesses.

In response to your request that we review the effectiveness of recalls of food products used in school food programs, this report addresses the following questions:

1. How do federal agencies notify states and schools about food recalls involving schools, and what actions did state and school food administrators take in response to recent recall notifications?

¹GAO, Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food, GAO-05-51(Washington D.C.: Oct. 6, 2004).

²GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007) and GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: January 2009).

- 2. How do federal agencies advise states and schools about disposal of and reimbursement for recalled products, and what were state and school food administrators' experiences with the disposal and reimbursement process?
- 3. How did federal agencies assess the effectiveness of recent recalls, and to what extent do these assessments ensure that recalls are being carried out effectively in schools?

To address these questions, we reviewed recent holds and recalls of products from four companies: 1) the 2009 Peanut Corporation of America peanut products recalls; 2) the January and February 2008 Westland/Hallmark beef holds and recall; 3) a series of recalls from December 2007 through February 2008 of canned vegetables by the New Era Canning Company; and 4) a December 2007 administrative hold on Glacier Sales Inc. potato rounds. These events were selected to include recalls that took place over the last two years and include examples of recalls announced by both FDA and FSIS, as well as administrative holds initiated by FNS. To determine the role of federal agencies in carrying out food holds and recalls involving schools, we reviewed relevant regulations, policies, and guidance related to food holds and recalls, and interviewed officials from USDA, including FSIS, FNS, and the commodity procurement agencies, including the Agriculture Marketing Service and the Farm Service Agency; as well as FDA, the U.S. Department of Education, and the Centers for Disease Control and Prevention (CDC). Through interviews with federal officials and reviews of documentation they provided on recent holds and recalls from the four companies, we determined how the federal agencies carried out their role of notifying states and schools of suspect products. This included determining how they provided identifying product information and disposal instructions, and how they ensured that recalls were carried out effectively, as well how they reimbursed states and schools for selected recalls of commodity foods. To understand the experiences of states and school districts during food holds and recalls, we conducted site visits to state agencies and to school districts that state officials identified in California, Indiana, Pennsylvania, Texas, and Virginia. We also conducted site visits to school districts in Michigan and New Jersey that were identified in federal documents as being affected by recalls. After the peanut recall was announced, we added Minnesota and Idaho to our selected states and interviewed state and school food administrators from those states about the peanut product recalls. In total, we reviewed documentation and interviewed officials from 23 school districts, representing hundreds of schools subject to commodity and commercial recalls; however, this

information cannot be generalized to all schools. We selected states and school districts primarily for their experiences with one or more of the four food holds and recalls that are the focus of this report; but, also to ensure variation in geographic dispersion of states, school district size, and quantity of recalled products. In two states, we also interviewed distributors of food products to schools. To analyze how federal agencies assessed the effectiveness of recent recalls, we reviewed documentation on federal agencies' oversight and assessment of recent recalls and interviewed federal officials. We also interviewed officials from the national and state-level School Nutrition Association, the American Commodity Distribution Association, and the Center for Science in the Public Interest to obtain their views on food safety in schools. Further, we coordinated our review of how the Westland/Hallmark recall affected schools with the USDA Inspector General's broader evaluation of FSIS management controls over pre-slaughter activity, published in November 2008; ongoing evaluations of the FSIS effectiveness checks for the Westland/Hallmark recall; and USDA purchase specifications for ground beef used in federal food programs, such as school meal programs.³

We conducted this performance audit from May 2008 to August 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions, based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Schools Receive Food Through a Complex Distribution Network The distribution of food, including processing of food into different products, can be extensive and complex, with school districts receiving products from various sources. Once a food is produced by a particular company, it can travel to distributors, retailers, and/or processors before reaching schools. Sometimes large school food authorities can receive food directly from the originating company, but it is more typical for the

³U.S. Department of Agriculture, Office of Inspector General, Audit Report: *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, 24601-0007-KC, (Washington, D.C., Nov. 2008).

food to travel through these middlemen. This complex distribution path can make it difficult to track food from beginning to end, a problem which arises during food recalls when distributors, processors, and retailers must determine and inform states and school districts which products were produced with recalled foods and which were not. Because this identification process does not occur all at once, FNS, states, and school districts sometimes learn about affected products over time (see Fig. 1).

Company

School district

Processors

Figure 1: Possible Food Distribution Routes from a Company to Schools

Sources: GAO analysis; Art Explosion (images).

One component of the food distribution system that adds to the complexity of tracking individual ingredients is processing, whereby

D = DistributorsR = RetailersP = Processors

companies turn a food into one or more new foods. For example, according to USDA, Westland/Hallmark sent much of the commodity ground beef that it produced directly to processors and, sometimes, distributors. Distributors sent the beef to school districts, while further processors used the ground beef to create products schools can more readily use, such as meatballs and hamburger patties. Processors then sent these products to school districts, either directly or through distributors.

Federally Subsidized School Meal Programs

Federally subsidized school meal programs, such as the National School Lunch Program, are administered by USDA's Food and Nutrition Service (FNS), but several other USDA agencies are involved in procuring foods for the programs. FNS works with states to administer the school meal programs through local school food authorities. FNS subsidizes the school meal programs through donated commodities and cash payments. USDA's Agricultural Marketing Service (AMS) purchases commodities such as beef, poultry, fish, egg products, fruits, and vegetables, while the Farm Service Agency (FSA) purchases commodities such as grains, peanut products, dairy products, and oils for the school meal programs and other commodity distribution programs. FNS officials estimate that almost 50 percent of these commodities are further processed. In some instances, USDA contracts directly with processors, while in other instances, states and school districts contract with processors and USDA diverts commodities to processors on the schools' behalf to make specific foods, such as sending commodity beef to a processor to be turned into beef for tacos. Schools also use federal cash subsidies and their own operating monies to procure food and processed food products commercially, not involving USDA agencies.

Food Recall and Hold Procedures

Food holds and recalls to protect consumers are governed by various laws, regulations, and policies. ⁴ There are a series of events that typically

⁴FDA, Regulatory Procedures Manual, (Washington D.C., Mar. 2009); FSIS, Recall of Meat and Poultry Products, Directive 8080.1 Revision 5, (Washington D.C., Nov. 2008); USDA, Commodity Hold and Recall Process, (Washington D.C., July 2001). The FDA manual provides policy, responsibilities and procedures for FDA staff to initiate, review, classify, publish, audit and terminate recall actions. The FSIS directive provides responsibilities and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products. FNS officials said they use the USDA procedures for handling commodity holds and recalls. This document—developed jointly by FNS, FSIS, the Agricultural Marketing Service, and the Farm Service Agency—defines federal, state, and local agency roles and obligations.

precede a food hold or recall. Federal agencies—FSIS, FDA, or CDC—can become aware of a problem when a company identifies a problem and independently announces a recall, through inspections, product testing, or an outbreak of a suspected food-borne illness. CDC works with state health departments to identify the specific food or product involved. Once the product and its source are identified, either FSIS or FDA—whichever has jurisdiction over the product—works with the affected company to conduct a food recall. Neither FSIS nor FDA has "mandatory recall authority"—the ability to force a company to recall a product. However, both FSIS and FDA can request that a company recall a product and, in most cases, the company complies. Either FSIS or FDA then classifies the recall from Class I to Class III:

- Class I: A recall of food that poses a reasonable probability of causing serious, adverse health consequences or death. The PCA peanut product recalls were designated Class I because of the presence of *Salmonella*; the New Era canned vegetables recall was Class I because of the potential for botulism contamination.
- Class II: A recall of food that poses a remote probability of adverse health consequences. The Westland/Hallmark beef recall was designated as Class II because of a remote probability of adverse health consequences due to proper inspection procedures not being followed at the meat processing plant.
- Class III: A recall of food that will not cause adverse health consequences, but does not meet product specifications. For example, a product that might contain the presence of an undeclared, otherwise safe substance, such as excess water.

When a USDA commodity product is identified in a recall, FSIS or FDA contacts FNS. FNS then works with AMS or FSA to obtain more information on the affected commodity products. FNS then contacts the state agencies to whom it provided the product. The state agencies then

⁵Should a company fail to voluntarily recall a product, the FSIS and FDA have methods to remove products from commerce, such as product seizure.

⁶FSIS makes a determination of the recall classification at the time the recall is announced. FDA does not make a recall classification until after further evaluation; however, FDA makes an initial decision of how to treat the recall, based on known information about the recall at the time. For example, FDA treated the PCA peanut product recall as a potential Class I recall before it actually classified the recall because of the products' association with *Salmonella*.

notify school districts, who then notify the responsible persons at individual schools. Under USDA procedures, FNS is directed to notify states within 24 hours of learning of a recall, and then the states are expected to notify schools within 24 hours of receiving a recall notice from FNS. This process is used only when USDA commodities are involved, which account for 15 percent to 20 percent of the products used in school meals (see Fig. 2).

Figure 2: Simple Diagram of How Schools are Notified of Commodity Recalls **USDA HHS FSIS FNS FDA** Notifies affected

states of recall Releases Releases recall recall **AMS FSA** information information Identifies Identifies commodities commodities affected by affected by the recall the recall State agency Notifies schools of recall School district Locates recalled products at district and school-level

Sources: GAO analysis; Art Explosion (images).

If a state agency has FNS divert bulk commodity products on its behalf to a processor and the commodity is subsequently recalled, the appropriate procurement agency notifies the processor to which the commodity had been diverted. FNS does not alert the states as to which processors were affected. If a state or school food authority procures food commercially, which accounts for 80 percent to 85 percent of products used in school meals, neither FNS, FSIS, nor FDA is responsible for notifying states and schools; the school food administrator is typically notified directly by a distributor, wholesaler, or whoever sold the school district the food. Once schools are notified, recalls can expand if investigations reveal problems with products, in addition to those initially recalled. For example, FDA or FSIS may discover that problems at a particular manufacturing plant are more longstanding than initially thought. In these instances, the recalling firm could issue additional recalls for other products or time periods. As a result, schools could end up serving affected products between the first and subsequent recalls.

In this report, we address holds and recalls by four companies which affected schools.

PCA Peanut Product Recall

From January 2009 through March 2009, PCA issued a recall—and expanded the recall on three separate occasions—for products it supplied. The companies that received or used its products also issued recalls, covering almost 4,000 types and brands of peanut-containing products. Recalls were initiated after CDC, FDA, and state investigations of illnesses suspected of being food-borne revealed *Salmonella* in peanut butter manufactured by PCA. *Salmonella* is an organism that can cause severe illness, particularly in the elderly, young children, and others with weakened immune systems. Since peanuts are under its purview, FDA posted PCA's recall notices and monitored the recall as it developed. Schools in four states—Arkansas, California, Idaho, and Minnesota—received recalled commodity peanut products through the school meal programs that had not been further processed. In addition, commodity peanut butter was shipped to a further processor, which then distributed effected processed products to other states.

Westland/Hallmark Beef Holds and Recall

In January 2008, an animal protection organization released an undercover video of persons trying to force non-ambulatory⁷ cows to stand and walk

 $^{^7\}mathrm{USDA}$ defines "non-ambulatory" cattle as those that cannot rise from a recumbent position or cannot walk.

at the Westland/Hallmark meat processing plant in Chino, California. Because of the mistreatment of the cattle, on January 30, 2008, FNS issued a 10-day hold on all commodity ground beef produced by Westland/Hallmark since October 1, 2006.8 On February 8, 2008, FNS extended the hold for 10 additional days. On February 17, FSIS announced a recall by Westland/Hallmark, designated as a Class II recall, of more than 143 million pounds of beef produced over a two-year period from February 1, 2006, to February 2, 2008, because proper inspection procedures were not followed when cows that had become non-ambulatory were not reinspected before they were slaughtered. There were no problems found during FSIS testing of meat that was delivered for school meal programs, but concerns remained among Congress and others because non-ambulatory cows may pose an increased risk of bovine spongiform encephalopathy, also known as mad cow disease, linked to a rare but fatal degenerative brain disease in humans.

FNS estimated that over 7,000 school districts in 46 states and the District of Columbia were involved in the recall of commodity beef products. FNS also estimated that approximately 50 million pounds of suspect Westland/Hallmark commodity ground beef was provided to schools, of which approximately 30 million pounds were served prior to the recall and about 20 million pounds destroyed as a result of the recall. FSIS and FNS were not aware of any schoolchildren or any other persons getting sick from eating the recalled beef.

New Era Canned Vegetables Recall The New Era Canning Company issued a recall in December 2007 and expanded this recall on three subsequent occasions in early 2008, covering numerous types of New Era canned vegetables. These products had been distributed nationwide as part of the USDA commodity program and were sold commercially under 10 different brand names over a five-year period. These products were recalled because the vegetables had not been adequately heated during the canning process and could have contained a bacterial toxin which causes botulism, a potentially life-threatening illness. According to FDA and FNS officials, there were no reported illnesses

Source on tracts with companies like Westland/Hallmark to provide commodities for the school meal programs. These contracts prohibit the mistreatment of animals; so when AMS became aware that Westland/Hallmark was mistreating cows, it suspended its contract and worked with FNS to place a hold on Westland/Hallmark beef. While FNS issued a hold for a contractual violation, FSIS issued a recall because Westland/Hallmark did not follow inspection procedures that require a veterinarian to reinspect non-ambulatory cattle before slaughter.

attributed to recalled products and FDA reported that no toxins were found in product testing. The multiple recalls were the result of FDA, the Michigan Department of Agriculture, and New Era identifying additional products and time periods that could be affected.

FNS officials reported that schools in 37 states received New Era products through the USDA commodity program. Schools received 516,432 cases of the recalled canned beans, but had only 13,931 cases remaining at the time of the recall. It is unknown how many cases states and school districts purchased commercially.

Glacier Sales Potato Rounds Hold On December 3, 2007, FNS issued an administrative hold on Glacier Sales potato rounds because of texture, taste, and odor issues. FNS officials said that Glacier Sales subsequently withdrew the product and worked with school districts to arrange reimbursement and/or replacement. FNS reported that 5 states had schools that were affected and that 6,480 cases of the product were involved during the hold, though additional states were affected once the company issued a withdrawal notice. Subsequent testing of the potato rounds found no health or safety problems.

Despite Its Efforts, FNS Did Not Always Ensure that States and Schools Received Timely and Complete Information about Potentially Dangerous Commodity Products in Three Companies' Recalls

As a result of a number of factors, FNS did not always ensure in our three recall cases that states and schools received timely and complete notification about suspect food products provided to schools through the federal commodity program. First, USDA has procedures that explicitly allow FSIS to provide FNS with immediate notification of investigations that could involve commodity products, which could allow FNS to issue a precautionary hold on the suspect product, but FDA and FNS do not have similar formal protocols. Second, in two recent recalls we reviewed, FNS followed the lead of the FDA, and removed foods from school meals when they were officially recalled, but did not work with FDA and the USDA procurement agencies to place a hold on the products when it first became aware of food safety issues at facilities that supplied commodities. Third, in its recall notices, FNS did not provide complete and accurate available information that would be needed by schools to identify all affected products in their inventory, particularly for processed products. In addition, states did not always provide schools with timely and complete information. FNS tried several mechanisms to provide information directly to schools; however, these did not work as intended either for content or timeliness. As a result, in some cases, schools served affected products in school meals. FNS is aware of these factors, and is taking a number of steps to improve its processes.

FSIS Has Procedures that Allow it To Provide FNS Early Notification of Investigations involving Commodity Products; however, FDA Does Not, Which Could Limit FNS's Response

When FSIS learns a food within its regulatory jurisdiction—such as meat or poultry products—may be adulterated or mislabeled, USDA procedures allow for immediate notification of FNS. FSIS alerts FNS and the procurement agency, such as AMS, that there is a potential recall. In consultation with others, FNS determines whether to put a temporary hold on the product. If FNS decides to issue a hold, it notifies states and schools so they can remove the commodity products from school menus, pending additional testing and data collection. FSIS convenes a committee which, when commodities are involved, includes representatives of FNS and other agencies.

In the case of the Westland/Hallmark beef recall, FNS placed a hold on commodity beef products from the California plant prior to the publicly announced recall; however, in this case, the hold did not result from communication with FSIS. Instead, FNS officials said that following the media coverage of inhumane practices at the plant, they consulted with AMS and initiated a hold on January 30, 2008, for beef products produced at the Westland/Hallmark plant. However, rather than placing a hold on all products produced at the plant; the hold only covered products produced after October 1, 2006. FSIS officials said that they did not have an ongoing investigation at the time, but that a USDA investigation was started soon after. According to FNS officials, they were subsequently included in FSIS recall discussions, and on February 17, FSIS announced the recall. The recall covered a longer time frame than the FNS hold—including all beef produced after February 1, 2006—as a result, some schools could have served recalled beef produced between February 1, 2006, and October 1, 2006, during the FNS hold, even though this beef was later recalled.

Although FNS works to help ensure the safety of USDA commodities that may be served in schools, FNS stated that it is not responsible for taking food safety actions for products commercially procured by schools. This distinction led to confusion and potential risk of consuming affected products when schools purchased Westland/Hallmark beef commercially during the FNS hold on Westland/Hallmark commodity beef. For example, a school district in California told us that during the FNS hold, some of its processors believed that Westland/Hallmark commercial products were safe, claiming that only Westland/Hallmark commodity beef was affected. School district administrators said they explained to the processors that they did not want to receive any Westland/Hallmark product, and commercial products were subsequently included in the FSIS recall, suggesting the school district, had it believed the processors, would have served the suspect meat to school children.

Unlike FSIS procedures, FDA procedures do not specifically provide for immediate notification of FNS when FDA investigations include commodity products, although agency officials stated that they communicate frequently. FDA is responsible for the safety of virtually all food products, except for meats, poultry, and processed egg products. FDA procedures require FDA notify USDA agencies, including FNS, "of recalls of FDA-regulated products that have been distributed to any USDA agency that may have involvement with the school lunch program."9 However, the procedures do not give any indication that FNS can be included in the recall deliberations, as they are when an FSIS food is concerned. According to FDA officials, FNS was included in discussions and email correspondence during the investigation of the Salmonella outbreak that was traced to peanut products, but FDA did not provide us with information about notifications provided to FNS during the investigation of the New Era plant. According to FNS and FDA officials, they are working together with AMS and FSA officials on developing a memorandum of understanding that will provide for specific notification to FNS, AMS, and FSA during FDA investigations that may involve commodities intended for school meal programs. However, the agencies have not established a time frame for completing the memorandum of understanding.

FNS Waited to Take Action on Commodity Products until New Era and PCA Issued Recall Notices Affecting Commodity Products Instead of Using Available Information to Initiate Administrative Holds after Initial Recalls

FNS and USDA procurement agencies determined whether commodity products were involved after receiving FDA announcements of recalls of New Era and PCA products. For the initial PCA recall on January 13, 2009, FNS officials said that the FSA, which procures food for USDA commodity programs, checked for commodity peanut butter purchases for school meal programs from PCA's Blakely, Georgia plant, and found that there were none within the time period identified in the notice, so FNS did not notify states to take any precaution with commodity peanut products. Subsequently, after two FDA announcements of recall expansions, on January 23, 2009, FNS posted to its Web site a statement that none of its commodities were affected by the PCA recall. Five days later, on January 28, 2009, following additional inspection and review at the Blakely plant, FDA announced another PCA recall notice, which expanded the manufacturing dates and products subject to recall. Upon learning of the January 28 expanded recall, FNS worked with FSA to determine if commodities were affected. FNS informed the affected states of the

⁹FDA Regulatory Procedures Manual.

recalled commodity products the following evening. Similarly, after the first New Era recall announcement in December 2007, FNS officials said that AMS checked for commodity canned bean purchases from New Era and found that it had purchased other products from New Era, but not those that were part of the recall, so FNS did not notify states to take precautions with New Era commodity products. In January 2008, New Era expanded its recall to include additional products. FNS worked again with AMS which, this time, determined that commodity products were affected. The following day, FNS informed affected states of the recall.

FNS did not issue administrative product holds after it was notified about initial recalls of New Era and PCA products. In both the PCA and New Era situations, the initial recalls did not include commodity products; but in both cases, commodity products were eventually recalled because the recall was expanded either to include products manufactured over a longer time period or to include more products manufactured at the same plant. USDA hold and recall guidance does not indicate what factors and criteria FNS should consider when determining whether to institute an administrative hold. FNS, in consultation with the responsible procurement agency, could have placed a hold on all commodity products produced by these companies when it became aware of a potential food safety issue, regardless of when the products were produced, particularly given the serious health risks of botulism and Salmonella potentially posed by the recalled products. Instead, FNS relied strictly on the recall notices and only notified schools about the potential hazards of commodity products after the firms had expanded their recalls to specifically include products purchased through the commodity program.

Because FNS did not immediately place a hold on all PCA peanut products and New Era canned vegetable products at the time of the initial recall, children may have possibly consumed these products through the school meals programs—products that were later included in the expanded recalls. According to the CDC, of the 691 individuals sickened, 226 were school-aged children, of which 46 were hospitalized due to consuming *Salmonella*-contaminated peanut products. ¹⁰ CDC does not have information on how many of the children may have consumed the products in school. ¹¹

 $^{^{10}\}mathrm{CDC}$ provided data for persons aged 5 through 18 for use as school-aged children.

¹¹Data from CDC, as of March 24, 2009.

FNS Notifications to States about the Westland/Hallmark Recall Did Not Always Provide Complete Information, Particularly on Processed Products

In the Westland/Hallmark case, FNS officials said that they notified states on the same day they learned of the recall affecting commodity products, but FNS's initial recall communication did not provide states with complete and accurate information that was needed by schools to identify all affected products on their shelves. ¹² The initial recall communication issued by FNS informed states that the products that had been subject to hold were now being recalled, but did not inform states which specific processed Westland/Hallmark beef commodity products, such as sloppy joe mix, frozen beef patties, and other items offered by FNS to states to order for school meal programs, were also subject to the recall. It was not until February 26, 2008—almost four weeks after the original hold was issued—that FNS notified states that these further-processed products contained recalled beef. The longer recalled products remain unidentified, the greater the risk that these products could be inadvertently consumed.

FNS also did not provide states and schools with information to identify the processors of products containing Westland/Hallmark beef in instances where commodity beef ordered by states in bulk from FNS was provided directly to processors. In addition to allowing states to order processed commodity products from USDA, the Department also allows states to have FNS bulk commodities, such as beef, diverted directly to processors of the state's choosing for further processing. During the Westland/Hallmark hold, FNS notified further processors, providing them information that allowed them to identify affected beef products. FNS also advised states in its recall instructions to contact their processors to determine if their state or schools had received further processed food containing recalled beef. USDA's procedures do not specify how and when processors are to inform states and schools of recalled products and, as in the Westland/Hallmark recall, FNS officials said that they did not oversee this notification to ensure that further processors promptly inform states and schools. Moreover, although FNS knew which further processors received affected Westland/Hallmark beef, it did not provide the names of these further processors to states and schools, because FNS considers it the responsibility of the processor to contact consignees, in this case states and schools. As a result, states and schools had to wait for further processors to identify and inform them of affected products. Some school food administrators told us that they received information from further processors for some products weeks after the initial Westland/Hallmark

 $^{^{12}\}mbox{USDA}$ guidance provides that FNS notify states within 24 hours of learning of a recall involving commodities.

holds announcements, during which time affected products were served in some school meals.

Moreover, in its initial administrative hold notice, FNS did not alert states that further processors often commingle beef from multiple sources to create end products, which means that states and schools could receive affected end products, even if the bulk beef they diverted to further processors came from a plant other than Westland/Hallmark. After the Westland/Hallmark administrative hold was announced, identifying the affected beef, officials in one state said they assumed all its further processed beef products were not affected, because it had not had FNS divert Westland/Hallmark beef to processors on its behalf. However, almost three weeks after the hold announcement, the state said it learned from FNS that beef processors often commingle commodity beef and realized some of its further processed products were made, in part, with affected beef from other states. Due to the confusion, schools in the state had likely been serving products in school meals for several weeks which should have been put on hold. FNS officials told us that they are in the process of rewriting the USDA recall procedures and it will address processors and further processed products; however, FNS officials said that they have not established a time frame for completion.

States Did Not Always
Provide Timely and
Consistent Information to
School Districts on Holds
and Recalls, but Some
School Districts Took the
Initiative to Hold Products
as They Waited for More
Information

Although USDA procedures direct states to notify affected schools within 24 hours of receiving a recall notice from FNS, states did not always forward the information within this time frame and schools sometimes received critical information days later. FNS announced its administrative hold on Westland/Hallmark beef on January 30, 2008, but in one state, a school official told us that she did not hear about the hold from the state's technical assistance office until five days later, on February 4, 2008. Similarly, after the Sunday, February 17, 2008, USDA announcement of the Westland/Hallmark beef recall, officials in four of the five states we interviewed said they did not notify schools until after the Monday holiday, on Tuesday, February 19, Wednesday, February 20, or Thursday, February 21. Officials in one state in which schools were open on the Monday federal holiday said that they were unable to provide information schools requested, because the FNS regional office was closed for the holiday. For the New Era recall of canned vegetables, officials in another school district told us they found out about the January 18, 2008, recall when FDA investigators showed up at the school five days later, on January 23, 2008, to check their compliance with recall procedures; FDA investigators and school officials did not find any affected product remaining in inventory. Later that same day, school district officials said

they received an email from the state informing them they had received a truckload of affected canned green and garbanzo beans several years before. State officials said they did not initially forward information about the recall because they assumed that the product was so old it was likely consumed.

After receiving information about the Westland/Hallmark hold from FNS, indicating that further processors were responsible for notifying states of further processed products containing Westland/Hallmark beef, states gave different instructions to school districts on what to do about the hold, resulting in different responses. For example, at the beginning of the beef hold, one state said that it instructed its school districts to place all processed beef products on hold until processors had time to figure out which items were affected and which were not. As a result, this state's schools had all affected beef on hold. On the other hand, according to a school district in a different state, the state did not instruct its school districts to place all beef products on hold and state officials did not initially realize that some processed products could also be affected. A few days after the initial hold announcement, state officials determined processed products from one processor could be affected and sent school districts an email informing them that many additional processed items were subject to the hold. As a result, a school district in this state told us that its schools may have served affected products in the interim.

Some school districts took the initiative to hold suspect products, pending final notification about all products affected by the recalls. In the case of Westland/Hallmark, some schools told us that media and parent inquiries about the safety of the meat served in schools prompted them to remove all beef from their school lunch menus after the initial recall. One school district in California, in an abundance of caution, did not serve beef for the remainder of the school year. Because they stopped serving any beef products after the recall announcement, these school districts did not risk serving products, including processed products, that were later identified as the recall unfolded and expanded.

FNS Has Used
Supplemental Notification
Strategies, but Most Have
Not Resulted in More
Timely Notification to
States and Schools

Supplemental notification methods provide the potential for FNS to communicate recall information directly to schools in a more timely manner than under the standard notification procedures. The standard USDA procedures allow FNS 24 hours after learning of a recall involving commodities to notify states, and then allow an additional 24 hours for states to notify schools. Under this standard notification process, schools might not learn of a recall until 48 hours after it was announced by FSIS or

FDA, during which time, schools could unknowingly serve affected products. Although FNS could explore ways to reduce the standard notification time frames, supplemental notification methods providing information directly to schools, such as through email and Web site postings, could potentially provide schools with more timely information. ¹³

Because of the breadth of the recall, FNS officials said that they used the U.S. Department of Education's crisis communication email system to send email alerts directly to all schools about the Westland/Hallmark beef recall; but, this additional notification did not seem to improve communication to schools. FNS officials said this was the first time that they had used Education's crisis system to ensure schools received prompt notification. However, this communication was not sent until February 22, 2008, more than 3 weeks after FNS had placed the commodity beef on hold and 5 days after the recall was publicly announced. ¹⁴

FNS also employed its own newly-developed commodity alert system to notify school districts directly about the PCA peanut product recall, but the system did not appear to improve the content or timeliness of communications to schools. FNS' Commodity Alert System was designed to email "instant notices" on food safety issues to registered subscribers. According to FNS, the system was first used January 30, 2009, to communicate that the PCA peanut product recall included commodity products. However, the email was not sent until 2 days after FDA publicly announced an expanded recall of products containing suspect peanuts. More importantly, the email to subscribers did not identify the affected commodity products by name or the states or schools receiving them, but simply stated that "a limited number of [peanut] products were identified as being purchased by USDA." FNS said it did not include information on products or states affected because alert emails could not exceed 300 characters of text. FNS subsequently assessed how many of those who

¹³We have previously reported on the need for USDA and FDA to ensure that customers are notified promptly of food recalls and to determine if additional approaches are needed to alert customers. GAO-05-51.

¹⁴The notification, sent through the Department of Education's crisis communication system, went to school administrators and principals, not to school food service professionals.

 $^{^{15}}$ The commodity alert system was first used for the PCA recall. It was not developed until after the Westland/Hallmark recall.

 $^{^{16}}$ FNS officials have indicated that they have increased the number of allowable characters to 1000.

signed up for the service successfully received the January 30, 2009, email alert and found that 37 percent of those who completed the initial registration and who could have expected email alerts on important food safety problems did not receive the email due to problems with their registrations. FNS stated they would take steps to improve the registration process. In a subsequent alert, sent on March 17, 2009, regarding expanded PCA recalls of commodity peanut butter, FNS stated that two recall notices had been issued 20 days and 14 days earlier because USDA purchased peanut butter associated with the PCA Plainview, Texas plant.

FNS has also used its Web site to communicate food safety information to states and schools, but recent postings have not been timely or complete. FNS' food safety Web site notes, "Here you will find information on food safety and security related to the assistance programs administered by FNS, as well as links to FNS' food safety partners," and includes information under a heading, "Current Initiatives and Resources." However, we found only a single posting for the New Era canned vegetables recall and it addressed only the initial New Era recall and the first recall expansion, not the second and third recall expansions that involved commodities. According to the Web site, "No USDA-purchased commodities are involved at this time." The Web site did not inform states, schools, parents, and the public that two subsequent New Era recalls did include USDA-purchased commodities. For the PCA recall, FNS posted a statement on January 30, 2009, 2 days after FDA publicly announced an expansion of the recall, to say that a limited number of recalled products were identified as USDA purchases. However, the announcement did not say whether schools were affected, which states were affected, or what products were affected. Another USDA statement posted to the FNS Web site on March 6, 2009, explained that 10 days earlier, FNS had learned that commodity peanut butter purchased from Sunland Inc., and distributed to schools was made from peanuts roasted at PCA.

¹⁷These persons may have completed the initial registration and had received an email welcoming them to the system, but if they did not reply to the email to acknowledge receipt of the confirmation, they would not have completed their registration.

FNS Provided
Disposal and
Reimbursement
Instructions to States,
but State and School
Administrators
Reported Challenges
in Disposing of
Products and
Obtaining
Reimbursement

FNS Provided Disposal Instructions, but Not All Schools Followed Disposal Procedures and Some School Districts Reported Challenges in the Disposal of Recalled Beef

FNS provides disposal instructions to states that are specific to each recall; these instructions are then tailored by each state to meet state or local public health procedures. For example, for the Westland/Hallmark beef recall, FNS guidance instructed states and school food authorities with 50 cases or less to destroy the product on site, and render it unfit for human consumption by following guidance from state or local health authorities. If states or school food authorities had more than 50 cases, FNS guidance said to take the product to a landfill, have it incinerated, or send it for inedible rendering. States often revised the FNS notice before sending it on to school districts by changing the listed contacts or including additional disposal instructions specific to the state. For example, one state allowed its school districts to follow alternate methods of disposal suggested by local health departments.

Although all school districts we interviewed that had recalled products in their inventories reported disposing of them, ¹⁸ at least two school districts did not follow all instructions provided by FNS and state officials. For example, a school district official in one state told us her staff destroyed recalled New Era canned beans that had been opened by pouring the contents down the garbage disposal. FNS and FDA's notices said not to

¹⁸This refers to the New Era, Westland/Hallmark, and PCA recalls. Glacier Sales was an administrative hold.

open cans and the FNS notice said further, that if cans were already open, not to put the contents in a garbage disposal because of the risk of exposure to the toxin that causes botulism. Another district worked with its distributor, who was storing Westland/Hallmark recalled beef products, to divide the district's recalled beef among its schools so the district did not exceed 50 cases at any one location. School district officials said this allowed them to dispose of the products on site, rather than make special arrangements with a landfill, as specified in FNS destruction instructions for school districts with more than 50 cases of recalled products.

In some instances, the destruction and disposal of recalled product was delayed as school food administrators searched for a means of disposal, increasing the risk that these products could be inadvertently consumed. Five of the 15 school districts we interviewed that had affected Westland/Hallmark products in-stock reported challenges in disposing of affected beef products in landfills. For example, an official from one district found that the district's trash pickup company would not take 15,000 pounds of affected beef because they did not accept food. There was no local landfill, and a neighboring town's landfill also refused to take the beef. The food service director told us neither the state nor the city health department was able to help locate a disposal site. Finally, at the suggestion of someone in another state, the food service director arranged disposal at a landfill in another town, but the director had to arrange for delivery of the 15,000 pounds of meat to the landfill. The raw beef was buried, in accordance with state instructions. A school district in another state told us the city landfill would not accept raw beef; so after making inquiries, the food service director learned he could send the beef to a rendering company, which turns food into other products. For a fee, the rendering company collected the district's 400 cases of raw beef from the district warehouse. However, the rendering company required that all beef be removed from its packaging, so the food service director and his staff spent a few hours opening 400 cases and separating meat from its wrapping. Figure 3 shows a large quantity of beef from one school district at a transfer station, prior to being transported to a landfill for disposal.

LURIS

Figure 3: A School District's Large Quantity of Westland/Hallmark Beef Products at a Disposal Transfer Station

Source: Long Beach Unified School District.

Schools that had smaller quantities of recalled beef typically did not report difficulties in disposing of recalled products. FNS destruction instructions allowed school districts with smaller quantities to dispose of the suspect foods in their regular trash such as by opening packages, dousing the food with bleach, and double-bagging it to prevent consumption before placing it in the trash receptacle.

School districts also reported that disposal of commercially purchased foods was simpler as the processor or distributor typically collected and disposed the recalled products. Officials at some of the school districts we interviewed told us it was their distributor or processor who informed them of commercial recalls, and then collected any affected product and/or stopped delivery. For example, one school district reported that its distributor collected and disposed of commercially purchased Westland/Hallmark beef.

Some State and School Officials Said They Were Not Reimbursed for All Costs Incurred in Disposal and Found the Process Difficult Some school officials told us they were not reimbursed for all costs incurred due to recalls. ¹⁹ USDA guidance defines which expenses are reimbursable and which are not. Reimbursable expenses include some transportation, as well as storage, destruction, and processing costs. Schools and school districts are not reimbursed for administrative and personnel costs, including overtime paid to deal with a hold or recall, or for other foods purchased to replace recalled products.

However USDA guidance did not specifically address whether states can be reimbursed for commodities that have been processed with recalled ingredients, leading to inconsistencies in reimbursement in the Westland/Hallmark recall. After the Westland/Hallmark recall schools were either reimbursed for the recalled beef or received a replacement. However, officials in one state told us its schools were not reimbursed for the cost of other commodities that had also been used in recalled processed beef products, such as commodity tomatoes used to make spaghetti meat sauce. In contrast, a school district in Texas was reimbursed for commodity cheese it had sent to a further processor, along with commodity beef to make burritos and taco snacks. FNS officials told us that it reimbursed states for all commodity products, such as tomatoes and cheese, used in further processed products that were subject to recall.²⁰

Reimbursement and replacement for recalled commodity products varied by recall. For the Westland/Hallmark recall, school districts provided documentation on the quantity of recalled beef destroyed to the states, and the states served as the intermediary for FNS reimbursement and replacement. For disposal costs related to New Era recalled products, FNS officials said they reimbursed states for their disposal costs, who then reimbursed schools. Most school districts did not receive reimbursement or replacement of New Era products because in eight of the nine states that had recalled product, the quantities destroyed were so small, states did not request product replacement or reimbursement. FNS officials said

¹⁹Federal, state, and sometimes local agencies, as well as the recalling company, may play a role in the reimbursement or replacement of recalled products, as well as related expenses.

²⁰USDA procedures provide that schools typically receive reimbursement and replacement directly from the recalling firm, unless the firm goes out of business or delays reimbursement, in which case USDA will initiate action to provide reimbursement or replacement.

that only one state had a significant amount of the recalled products and that this state requested reimbursement which FNS provided.

Some school officials informed us that they found the overall reimbursement process confusing, and three states reported having to submit multiple claims. FNS general procedures and those specific to Westland/Hallmark did not explicitly describe all types of documentation necessary for reimbursement. One school district in Indiana reported that it was unclear what information was required for reimbursement and staff spent a lot of time removing the code stickers and other identifying labels from recalled products, thinking they would need to submit them to the state. They later learned the code stickers and labels were not required. The district submitted a claim, but was later asked by the state to submit additional documentation on disposal costs such as mileage and labor, so more staff time was spent assembling this information and resubmitting the claim.

Some school districts also found the reimbursement process to be lengthy. USDA procedures direct that reimbursement to states occur within 90 days (3 months) of a recall, and that states, in turn, reimburse school districts "in a timely manner." Districts in several states that were reimbursed for New Era and Westland/Hallmark claims reported that they did not receive payment until many months after the recalls. In at least one state, state officials reported that they received reimbursement more than 90 days after the Westland/Hallmark recall. After receiving reimbursement from FNS, states may also have contributed to delays in providing reimbursement to schools. For example, food service staff in California told us their district filed for reimbursement of about \$42,000 in March 2008 for Westland/Hallmark beef but had not been reimbursed by their state as of November 2008, eight months later. California state officials told us that reimbursement was delayed, in part, because the state could not disburse payments until the budget was passed, which occurred in late September.

Federal Regulators
Did Not
Systematically
Monitor and Assess
the Effectiveness of
Recalls and Holds in
Schools

Neither FDA nor FSIS Systematically Monitored the Effectiveness of Recalls for Schools

Although both FSIS and FDA have procedures to systematically conduct and document quality checks to determine whether recalls are carried out effectively, the procedures did not ensure these checks were done in schools affected by recent recalls of USDA commodities. These checks, called effectiveness checks by FSIS and audit checks by FDA, involve visiting or contacting a sample of affected consignees—entities that received a recalled product, such as distributors, hospitals, restaurants, and schools—and determining whether they were notified of a recall; all affected product was located; affected product was properly disposed; and all steps were completed in a timely manner. These checks help ensure that affected products are removed from the market and are not consumed. Both FSIS and FDA conduct quality checks of a sample of consignees, however, procedures differ and neither ensures that a sample of schools is included. In an overall review of FSIS and FDA food recalls, we also previously reported that the agencies' procedures for selecting the sample of companies to check did not ensure that all segments of a food distribution chain are included, as well as problems with the timeliness of the checks.21

FDA procedures do not require it to systematically monitor recalls in schools by explicitly sampling schools for audit checks, grouping consignees into categories, or reviewing audit checks by consignee category, such as schools. Nonetheless, many of the FDA audit checks for the New Era recalls were conducted in schools that may have received the product as a USDA commodity or procured it commercially. FDA officials said that although they are not required to do so, in this case, they tried to give schools preference for selection in the sample if a school was

²¹GAO-05-51.

identifiable from the available information. The FDA district coordinator told us that of 2,553 completed audit check reports on the New Era recalls, 823 were for schools. The district coordinator was able to identify schools for whom audit check report forms were completed by the name on the audit form or because the person who completed the form wrote "school" under consignee type. "School" is not listed as one of nine consignee types on the audit check form, which includes "retailer," "hospital," and others. Our review of the audit checks of schools in one of the states we visited indicated some schools were not properly notified or had not followed recall instructions. Also, in the remarks section of some of the FDA audit check forms, the preparer indicated the recall for the school was "ineffective" or "not effective." The FDA district coordinator for the New Era recalls said the completed audit check forms were grouped by category, including a category for schools, and that any problems that were identified on the forms were addressed. However, FDA did not have documentation of any analysis that was done for the schools as a group to determine whether there were systemic problems, nor did they have documentation of corrective actions taken.

FDA officials said that they conducted audit checks for the PCA peanut product recalls, and field staff were instructed to give priority to schools in making their selections for the audit checks, but only schools that procured the products commercially were included because the audit checks specifically excluded schools that received affected peanut products only through the school meals program. FDA officials said that they rely on FNS to conducts its own checks of schools that received affected commodities for school meal programs. FDA instructions for conducting audit checks for the PCA recalls included special provisions for selecting schools and other facilities that served vulnerable populations. However, at the time of our contact with FDA officials, they did not know if schools had procured affected peanut products commercially or had been selected for audit checks and did not have an assessment of audit check activity to date for schools or other consignees. According to FDA, the analysis of audit checks typically occurs further into the monitoring phase of the recall, closer to the termination phase of the recall.

FSIS procedures explicitly allow for grouping those to be contacted for effectiveness checks in categories such as schools, and selecting consignees from each category to create its sample. However, after the Westland/Hallmark recall, FSIS did not create a school category for its effectiveness checks, even though thousands of schools were affected. FSIS did ask FNS to provide names of schools and states affected by the

Westland/Hallmark recall of commodity beef and received a list of over 7,000 affected school districts, but FSIS officials did not use this information to include the schools in its effectiveness checks. FSIS effectiveness checks for the Westland/Hallmark beef recall did not include any schools that received the beef through the commodity program. FSIS estimated there were 9,500 consignees who received recalled Westland/Hallmark commercial beef, not including schools and others that had received Westland/Hallmark commodity beef for federally-subsidized food programs. FSIS officials said they did not know how many of the 9,500 consignees that had procured beef commercially were schools. FSIS determined its statistical sample would be 200 of the 9,500 consignees, using systematic sampling with a sampling interval of 47. Our review found 2 names of schools, the name of a preschool, and a school food distributor included in the sample; both schools that were selected procured the product commercially.

FSIS officials said they did not specifically include schools receiving recalled commodity products in their checks for the Westland/Hallmark recall, and FDA officials said they did not specifically include schools receiving recalled commodity products in their checks for PCA recalls, because they said that USDA was responsible for conducting its own checks of schools receiving commodities.

FNS Did Not Monitor the Effectiveness of Recalls or its Own Administrative Holds for Commodity Products in Schools

Although FSIS and FDA procedures direct them to monitor the effectiveness of recalls, they told us that they relied on FNS to conduct checks of schools affected by recalls of USDA commodity products; however, FNS does not conduct such effectiveness checks. FNS officials told us it was not their responsibility to check on the effectiveness of any of three companies' recent recalls covered in this review, but that they relied on their regulatory partners, FSIS and FDA, to conduct these quality checks. FNS has authority to issue holds on USDA commodity products, in conjunction with regulatory and procurement agencies, but does not have procedures in place to conduct a systematic review of schools to determine whether schools received notice of the hold and followed instructions to keep the identified products from being served to students.

²²FNS collects information on the disposition of recalled product through its reimbursement process, but this does not constitute an effectiveness check. As previously discussed, effectiveness checks confirm for a sample of consignees, such as schools, whether they had been notified and carried out the recall properly, including whether all affected products had been identified and disposed of properly.

FNS did not conduct such checks on its hold or hold extensions for Westland/Hallmark beef or Glacier Sales potato rounds.

Conclusions

Protecting school children from food-borne illnesses in schools depends on the efforts of many local, state, and federal entities. Agencies within USDA and HHS, including FSIS, FNS, and FDA, have critical roles in identifying food safety issues, disseminating information, providing guidance, and evaluating the effectiveness of food holds and recalls. While these agencies have related policies and procedures in place, recent recalls of products, from raw beef to peanut butter, have highlighted the importance of revisiting these policies and procedures to ensure they accomplish what they intend. Nearly 700 people, including over 200 school-aged children, were sickened by Salmonella during a 2009 recall of Peanut Corporation of America products and ingredients. And while it is not known to what extent the source of the bacteria in these cases of illness were from a school snack or meal, federal and state agencies must ensure schools receive timely notification, adequate information, and clear instructions on food holds and recalls. Evaluations also must be conducted to determine the effectiveness of those efforts. School children are a vulnerable population, in part because they are more likely to suffer complications from food-borne illnesses, and in part because they may have less knowledge to make informed choices about the foods they consume. As such, USDA and HHS should make the policy and procedure changes necessary to ensure that the food children consume in schools is unadulterated and safe.

The speed and complexity with which recalls unfold, often leading to multiple recalls of related products or covering longer manufacturing time frames, creates challenges for agencies and their efforts to protect consumers—particularly school children—from potentially harmful foods. Although FNS, in conjunction with the responsible USDA procurement agency, can issue an administrative hold on suspect products prior to a recall—an action taken in the Westland/Hallmark recall—the lack of criteria and guidance on when to issue a hold may have contributed to a conservative response to the New Era and PCA recalls, whereby FNS did not preemptively issue a hold on products that were later recalled. Absent guidance on when to issue administrative holds, FNS will continue to face challenges in deciding when to issue administrative holds. The ability to issue holds provides a valuable tool that allows FNS to act quickly to protect school children while investigations are ongoing. In addition, FNS and FDA officials said they are working on a memorandum of understanding about how the agencies will communicate during FDA food safety investigations. Such a document could provide FNS with important information when it considers administrative holds of suspect commodity products used in school meal programs. But, no time frame has been established for completing it.

Gaps in the protocols federal agencies follow in communicating with each other and gaps in states then communicating with schools districts have led to delays in schools receiving notice of recalls and sufficient information on what actions to take. These delays were, in some instances, exacerbated by difficulties in identifying processed foods that contained recalled ingredients, in part, because federal hold and recall guidance does not explicitly address the role of processors or distributors. As a result, some affected commodities were served to school children after holds and recalls were announced. In addition, insufficient guidance on disposal procedures for recalled products increased the risk that they could be inadvertently consumed. FNS officials said they have plans to address the role of processors and update the hold and recall procedures for USDA commodities, but have not established a time frame for completing the revisions. It is important for FNS to make changes to the procedures as soon as feasible to avoid confusion and delays the next time a major recall occurs that involves processed products.

Given the current technology for almost instant communication, it seems federal regulators could disseminate information through states to schools and directly to schools more quickly than the standard procedures, which permit up to 48 hours to elapse by the time FNS communicates with states and states communicate with schools. New strategies for federal regulators to communicate directly with schools, such as the FNS Commodity Alert System used for the PCA recalls, are promising but have yet to deliver timely or complete information. Further, although FSIS and FDA perform checks of how effectively recalls are carried out, neither agency systematically monitors or evaluates holds and recalls in schools. While FDA selected some schools for its New Era recall audit checks, it did not document its analysis of audit checks conducted at schools, nor did it track corrective action taken as a result of its audit checks of schools. Unless FSIS, FDA, and FNS revise their assessment procedures, these agencies will not be able to determine if additional actions are necessary to keep school children safe.

We have previously reported that food safety oversight is a complex and fragmented system requiring major improvements. Yet smaller, immediate improvements in coordination, notification, and evaluation procedures in the near term could better equip states and schools to protect their students from unsafe foods.

Recommendations for Executive Action

To better ensure the safety of foods provided to children through the school meal programs, we recommend the Secretary of Agriculture and the Secretary of HHS take 12 actions to make improvements in three areas related to recalls affecting schools: interagency coordination; notification and instructions to states and schools; and monitoring effectiveness.

We recommend the Secretary of Agriculture direct FNS and that the Secretary of HHS direct FDA to jointly:

 establish a time frame for completing a memorandum of understanding on how FNS and FDA will communicate during FDA investigations and recalls that may involve USDA commodities for the school meal programs, which should specifically address how FDA will include FNS in its prerecall deliberations.

We recommend the Secretary of Agriculture direct FNS to:

- develop guidelines, in consultations with AMS and FSA, to be used for determining whether or not to institute an administrative hold on suspect commodities for school meal programs;
- work with states to explore ways for states to speed notification to schools;
- improve the timeliness and completeness of direct communication between FNS and schools about holds and recalls, such as through the commodity alert system;
- take the lead among USDA agencies to establish a time frame in which it
 will improve the USDA commodity hold and recall procedures to address
 the role of processors and determine distributors' involvement with
 processed products, which may contain recalled ingredients, to facilitate
 providing more timely and complete information to schools;
- revise its procedures to provide states with more specific instructions for schools on how to dispose of recalled commodities and obtain timely reimbursement; and

• institute a systematic quality check procedure to ensure that FNS holds on foods and products used by schools are carried out effectively.

We recommend the Secretary of Agriculture direct FSIS to:

 revise its procedures to ensure that schools are included in effectiveness checks.

We recommend the Secretary of HHS direct FDA to:

- revise the Recall Audit Check Report form to include a consignee prompt for schools;
- revise FDA procedures to ensure schools are included in audit checks, either by drawing a separate schools-only sample or providing a selection preference for schools; and
- revise FDA procedures to ensure analysis of its audit checks is documented, and any problems with recalls or audit checks affecting consignees involved with schools identified and acted upon.

Agency Comments and Our Evaluation

We provided a draft of this report to USDA and HHS for review and comment. USDA stated that it generally agreed with and supported the recommendations of the report and provided additional information on the roles and responsibilities of all stakeholders involved in assuring the safety of food provided by USDA through its nutrition assistance programs. We have reprinted USDA's comments in their entirety in appendix I. HHS stated that it agreed with the recommendations of the report and that GAO has raised important issues regarding the safety of foods provided to children through the school meals programs. We have reprinted HHS's comments in their entirety in appendix II. Both USDA and HHS also provided technical corrections to the report which we incorporated, as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. We will send copies of this report to the Secretary of Agriculture, the Secretary of Health and Human Services, the Secretary of Education, and relevant congressional committees. In addition, this report will be available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-7215 or brownke@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix III.

Kay E. Brown

Director, Education, Workforce, and Income Security Issues

Kay C. Brown

List of Congressional Requesters

The Honorable George Miller Chairman Committee on Education and Labor House of Representatives

The Honorable Carolyn McCarthy Chairwoman Subcommittee on Healthy Families and Communities Committee on Education and Labor House of Representatives

The Honorable Rosa L. DeLauro Chairwoman Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Committee on Appropriations House of Representatives

The Honorable Richard J. Durbin United States Senate

Appendix I: Comments from the Department of Agriculture



United States Department of Agriculture

Office of the Secretary Washington, D.C. 20250

JUL 2 2 2009

Ms. Kay E. Brown Director Education, Workforce, and Income Security Issues U.S. Government Accountability Office 441 G Street, NW. Washington, D.C. 20548

Dear Ms. Brown:

We appreciate the opportunity to review the draft report, SCHOOL MEAL PROGRAMS: Changes to Federal Agencies' Procedures Could Reduce Risk of School Children Consuming Recalled Food (GAO-09-649) and to discuss the audit with Government Accountability Office (GAO) audit staff on May 1, and July 10, 2009. The health and safety of the children we serve in the Department of Agriculture (USDA) nutrition assistance programs is of the utmost importance to us. While we generally agree with and support the recommendations of the report, it is important that the report accurately reflect the roles and responsibilities of all stakeholders involved in assuring the safety of food provided by USDA through its nutrition assistance programs. Specific technical comments have been provided to GAO separately.

As Secretary of Agriculture, I oversee four agencies that each play a unique role relative to the food served in schools and oversight of the safety of that food. The Food Safety and Inspection Service (FSIS) regulates all meat, poultry, and egg products in commerce, including those products purchased by schools on the commercial market and those products purchased for use by schools through the USDA commodity programs. The Food and Drug Administration of the Department of Health and Human Services has oversight responsibility for the remainder of the food supply. Together, FSIS' regulations and inspections, along those of FDA, provide the foundation for the safety of food served in schools, including that obtained commercially and that from USDA-purchased commodity sources.

Other USDA agencies also play important roles in the process. The Agricultural Marketing Service (AMS) purchases USDA commodities, and AMS purchase contracts impose additional specification requirements for the commodities it purchases for schools. The Farm Service Agency (FSA), in addition to AMS, also procures USDA commodities using specific contractual requirements.

The Food and Nutrition Service (FNS) receives orders from State agencies for food requested by local school districts, and FNS fills those orders using commodity purchases made by both AMS and FSA. FNS serves as a conduit for information on any recall action taken by the two regulatory agencies, FSIS and FDA, or for administrative hold or recall actions requested by

Ms. Kay E. Brown Page 2

either AMS or FSA. FNS relies on the regulatory agencies, FSIS and FDA, for food safety assurances. Specifically, FNS relies on the regulatory agencies for early warnings about recalls that affect USDA-purchased commodities, information about recalls as they unfold when USDA commodities are affected, and assistance from their field staffs in conducting effectiveness checks or audits to assess the completeness of a recall that affects a USDA-purchased commodity.

Through the authorities of USDA agencies and FDA, we will continue to ensure that food served in schools is healthy and safe. USDA is committed to continuous improvement in our food safety responsibilities and actions based on best practices and information we learn from recall events.

We have already taken a number of steps to enhance capability regarding recalls; these actions include rolling out the web-based notification system in 2006, initiating a comprehensive revision of departmental hold and recall procedures, and drafting revised technical assistance materials on holds and recalls for State agencies and schools. We developed an arrangement with the Department of Education to broadcast a food safety message of significant public health concern to schools, and are working with FDA on a Memorandum of Understanding to allow sharing of information during an investigation and prior to an official announcement of a recall that affects USDA-purchased commodities. Overall, the goal is to streamline communications among departments, agencies, and State partners to yield a more effective and integrated approach to handling recalls.

Our comments above, and the technical comments we previously provided to and discussed with GAO staff, are consistent with the subject GAO report's recommendations to improve and strengthen the food safety system for USDA nutrition assistance programs. In conclusion, USDA will continue to work internally, and with HHS, to build a system that will assure the safety of the food provided and, thus, the health and well-being of all children that participate in our nutrition assistance programs.

Sincerely,

Thomas J. Vilsack Secretary

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation Washington, DC 20201

JUL 2 2 2009

Kay E. Brown, Director Education, Workforce and Income Security Issues U.S. Government Accountability Office 441 G Street N.W. Washington, DC 20548

Dear Ms. Brown:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "SCHOOL MEAL PROGRAMS: Changes to Federal Agencies' Procedures Could Reduce Risk of School Children Consuming Recalled Foods" (GAO-09-649).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Barbara Pisaro Clark

Acting Assistant Secretary for Legislation

Barbara Pisaro Clark

Attachment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville MD 20857

JUL \$2 2009

DATE:

TO:

Acting Assistant Secretary for Legislation

FROM:

Principal Deputy Commissioner of Food and Drugs

SUBJECT:

FDA's General Comments to GAO's Draft Report entitled, SCHOOL MEAL PROGRAMS: Changes to Federal Agencies' Procedures Could Reduce Risk of School Children Consuming Recalled Food (GAO-09-

FDA is providing the attached general comments to the U.S. Government Accountability Office's draft report entitled: SCHOOL MEAL PROGRAMS: Changes to Federal Agencies' Procedures Could Reduce Risk of School Children Consuming Recalled Food (GAO-09-0649).

FDA appreciates the opportunity to review and comment on this draft report before it is published.

> Joshua M. Sharfstein, M.D. Principal Deputy Commissioner of

Food and Drugs

Attachment

FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled, SCHOOL MEAL PROGRAMS: Changes to Federal Agencies' Procedures Could Reduce Risk of School Children Consuming Recalled Food (GAO-09-649)

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. GAO has raised some important issues regarding the safety of foods provided to children through the school meals programs. FDA continually strives to advance its public health mission, and this includes efforts to improve and strengthen communication among all agencies involved to ensure the safety of food products.

FDA's Specific Comments on GAO Recommendations for Executive Action

GAO Recommendation 1

We recommend the Secretary of Agriculture direct the Food and Nutrition Service (FNS) and that the Secretary of HHS direct the Commissioner of the FDA to jointly

 Establish a timeframe for completing a memorandum of understanding (MOU) on how FNS and FDA will communicate during FDA investigations and recalls that may involve USDA-commodities for the school meal programs, which could specifically address how FDA will include FNA in its pre-recall deliberations.

FDA Response

FDA agrees with GAO's recommendation and will continue to work with FNS to complete a MOU as soon as possible.

GAO Recommendation 2

We recommend the Secretary of Agriculture direct FNS to

• Work with states to explore ways for states to speed notification to schools.

FDA Response

FDA will offer its network to FNS to speed notification to schools. FDA will continue a close working relationship with FNS and stand ready to aid in any way possible within areas under our jurisdiction.

GAO Recommendation 4

We recommend the Secretary of HHS direct the Commissioner of FDA to

Revise the Recall Audit Check form to include consignee prompt for schools.

FDA Response

 ${
m FDA}$ agrees with ${
m GAO}$'s recommendation and is currently taking steps to implement the revision to the Recall Audit Check form.

We recommend the Secretary of HHS direct the Commissioner of FDA to

 Revise FDA procedures to ensure schools are included in audit checks, either by drawing a separate schools-only sample or providing a selection preference for schools.

FDA concurs that the best approach to protect public health is to ensure that special and vulnerable populations including, but not limited to, schools are covered as part of a broad recall audit approach. Currently, when FDA recall staff review consignee lists and decide which firms to include in audit checks, FDA notes and gives special consideration to special and vulnerable populations. Per GAO's recommendation, FDA will provide additional instruction to recall coordinators to continue to give special consideration to schools and other vulnerable populations during audit checks.

We recommend the Secretary of HHS direct the Commissioner of FDA to

 Revise FDA procedures to ensure analysis of its audit check is documented and any problems with recalls or audit checks affecting consignees involved with schools identified and acted upon.

FDA agrees with GAO that having as much information as early as possible regarding the results of a recall would be ideal. However, during large-scale, complex recalls, fully compiling and documenting recall results is challenging because the FDA recall coordination staff involved are overseeing the recall as it unfolds.

Response to Recommendation 2, bullet 1: R/D:GLewis:7/2/09
Edits:FNS-Marion Hinners:7/8/09
Revised:GLewis:7/9/09
Cleared:NBeru:7/10/09
Edits:CAinsworth:7/13/09
Edits/Cleared:BHarden:7/13/09
Cleared:LTarantino:7/14/09

Response to Recommendation 4 bullet 2: R/D:JThomas:7/10/09 Comments:OE:AZamora:7/10/09 Cleared:RWagner:7/10/09 Edits:CAinsworth:7/13/09 Edits/Cleared:BHarden:7/13/09 Cleared:LTarantino:7/14/09

Comments: Y.Jenkins/C.Grillo/D.Foellemer: 7/15/09

Edits: Y. Jenkins: 7/16/09

Cleared with Edits: V. Madamba (OCC): 7/20/09

Edits based on Teleconference with JM Sharfstein: 07/21/09

Responses to Recommendation 1, bullet 1 provided by: ORA

Responses to Recommendation 4, bullet 1 provided by: ORA Responses to Recommendation 4, bullet 2 provided by: ORA (blue) and CFSAN (black)

Responses to Recommendation 4, bullet 3 provided by: ORA

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contact	Kay E. Brown, (202) 512-7215, or brownke@gao.gov
Acknowledgments	In addition to the contact named above, Kathryn A. Larin, Assistant Director; Sylvia Arbelaez-Ellis; Susan L. Aschoff; Susannah L. Compton; Jean L. Cook; Sarah A. Farkas; Alexander G. Galuten; Nisha R. Hazra; Lise L. Levie; Daniel S. Meyer; and Charles E. Willson made key contributions to this report.

GAO's Mission	The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.
Obtaining Copies of GAO Reports and Testimony	The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday afternoon, GAO posts on its Web site newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to www.gao.gov and select "E-mail Updates."
Order by Phone	The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's Web site, http://www.gao.gov/ordering.htm.
	Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.
	Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.
To Report Fraud,	Contact:
Waste, and Abuse in	Web site: www.gao.gov/fraudnet/fraudnet.htm
Federal Programs	E-mail: fraudnet@gao.gov Automated answering system: (800) 424-5454 or (202) 512-7470
Congressional Relations	Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400 U.S. Government Accountability Office, 441 G Street NW, Room 7125 Washington, DC 20548
Public Affairs	Chuck Young, Managing Director, youngc1@gao.gov , (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548